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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,938	09/13/2005	Piero Del Soldato	026220-00058	8653

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ARENT FOX LLP  
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WASHINGTON, DC 20036

EXAMINER
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BIANCHI, KRISTIN A

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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05/13/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
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Patent\_Mail@arentfox.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,938	<b>Applicant(s)</b> DEL SOLDATO ET AL.	
	<b>Examiner</b> KRISTIN BIANCHI	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/09/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 3,6-8,10 and 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,9,11 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,5,11 and 21-23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-23 are pending in the instant application. Claims 3, 6, 7, 8, 10, and 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected subject matter. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference which anticipates one group would not render obvious the other. Claims 1, 2, 4, 5, 9, 11, and 21-23 are rejected. Claims 1, 2, 4, 5, 11, and 21-23 are objected.

### ***Response to Remarks***

The remarks filed on December 9, 2008 have been fully considered. In regards to the 35 U.S.C. 103(a) rejection of claims 1, 4, 5, 9, 11, and 21-23, Applicants' argue that "Del Soldato I and Del Soldato II should be disqualified as a reference under 35 U.S.C. 103(c) because 'the subject matter [of the reference] and the claimed invention were, at the time of the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.'" This argument has been found to be fully persuasive and the 35 U.S.C. 103(a) rejection has been withdrawn.

### ***Election/Restrictions***

Applicants' election with traverse of group I and the species N-[4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]phenylsulfonyl]-4-nitroxy-butanamide in the response filed on July 15, 2008 is acknowledged. The grounds for traversal as well as the examiner's explanation of why there is a lack of unity of invention are described

in the office action dated September 8, 2008. The restriction in accordance with the rules of lack of unity of invention is still deemed proper and is maintained.

The examiner will follow the guidelines of MPEP 803.02 wherein once a species is elected, it is examined for compliance with all applicable statutes for patentability and if compliance is found, then the examination is expanded to a reasonable number of elected species to determine whether they also comply with the statute. The examiner will determine whether the entire scope of the claims is patentable according to MPEP 803.02.

Applicants' elected species, N-[4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]phenylsulfonyl]-4-nitroxy-butanamide, appears allowable over the prior art of record. However, the claims which are readable on the elected species (i.e., claims 1, 2, 4, 5, 9, 11, and 21-23) are not found to be allowable (i.e., see rejection below). Even though the search of the elected species does not have to be expanded according to MPEP 803.02 (i.e., since the claims are not found to be allowable), the search of the Markush-type claim has been extended (i.e., to a reasonable number of elected species) to the non-elected species wherein:

M-T is 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide; and  
the rest of the variables are as defined in claim 1.

The Markush-type claims are rejected as follows and the subject matter of the claims drawn to nonelected species held withdrawn from consideration. Claims 1, 2, 4, 5, 9, 11, and 21-23 have been examined to the extent that they are readable on the elected embodiment and the above identified nonelected species. Since the claims

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were not found to be allowable, subject matter not embraced by the elected embodiment or the above identified nonelected species is therefore withdrawn from further consideration.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 9, 11, and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 defines M-T as the residue of M-TH or M-TOH wherein M-TH and M-TOH are defined as "COX-2 selective inhibitors wherein T = -SO<sub>2</sub>NH-, -SO<sub>2</sub>NR-, -CO-, -O-, -S-, -NH-, -N(SO<sub>2</sub>R)-, R being an alkyl with 1-10 carbon atoms, and wherein the COX-1 inhibiting activity/COX-2 inhibiting activity ratio (IC<sub>50</sub>) of the COX-2 selective inhibitor, M-TH or M-TOH, is greater than or equal to 5" without further limiting or disclosing a general formula for M. Applicants have not described the claimed genus of "COX-2 selective inhibitors" or defined M-TH and M-TOH in a manner that would indicate they were in possession of the full scope of this genus, or even to describe what this genus is comprised of. The limitation that "the COX-1 inhibiting activity/COX-2 inhibiting activity ratio (IC<sub>50</sub>) of the COX-2 selective inhibitor, M-TH or M-TOH is greater

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than or equal to 5" is not enough to meet the written description requirement for the definition of M-TH and M-TOH. The instant specification does not contain any guidance or description drawn to these COX-2 selective inhibitors except that the COX-1 inhibiting activity/COX-2 inhibiting activity ratio (IC<sub>50</sub>) of the COX-2 selective inhibitor, M-TH or M-TOH, is greater than or equal to 5 and the disclosure of five examples of compounds of formula (I). The five examples do not include a common general formula in their structures (i.e., for M) and therefore, they lack unity. There is insufficient description for the examiner to even determine the scope of the genus encompassed by the term "COX-2 selective inhibitors." Applicants have not described the claimed genus "COX-2 selective inhibitors" or M-TH and M-TOH in a manner that would indicate they were in possession of the full scope of said genus.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of

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sufficiently detailed, relevant identifying characteristics,” including, *inter aria*, “functional characteristics when coupled with a known or disclosed correlation between function and structure...” Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, the claimed “COX-2 selective inhibitors” or M-TH and M-TOH encompass any compound wherein the COX-1 inhibiting activity/COX-2 inhibiting activity ratio (IC<sub>50</sub>) of the COX-2 selective inhibitor, M-TH or M-TOH is greater than or equal to 5. This possible range of various structurally divergent compounds is far too broad as written and the definition of M-TH and M-TOH should instead be described by a general chemical formula. In other words, the way M-TH and M-TOH are described in the specification do not adequately allow one skilled in the art to ascertain that Applicants are in possession of the entire scope of the genus. Applicants have not described this genus in a manner that would allow one skilled in the art to immediately envisage the compounds contemplated for use. As such, the claims lack adequate written description for the claimed definition of M-TH and M-TOH or “COX-2 selective inhibitors.”

***Claim Objections***

Claims 1, 2, 4, 5, 11, and 21-23 are objected for containing non-elected subject matter.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/  
Primary Examiner, Art Unit 1626

Kristin Bianchi  
Examiner  
Art Unit 1626

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